33 Wood Avenue South, Ste. 466 Iselin, New Jersey 08830 TEL 732-603-3526 FAX 732-603-3532



Box Patent Extension Assistant Commissioner for Patents Washington, D.C. 20231 Attn: Ms. Karen Tyson

Re:

Application for Term Extension of

U.S. Patent No. 4,996,335 (the "Patent")

Dear Ms. Tyson:

Reference is made to our letter of April 13, 1998, a copy of which is attached.

As you discussed with our patent counsel, Mr. Allan Fanucci, and in order to clarify the record, please be advised that Bausch & Lomb Pharmaceuticals, Inc. ("BLP") is as this time the contingent sublicensee of the Patent. BLP is also a distributor for Pharmos Corporation.

We appreciate you willingness to allow us the opportunity to clarify the record. Please do no hesitate to call our corporate counsel Mr. Bruce Zivian, at (312) 917-9900 should you have any questions.

Sincerely,

Pharmos Corporation

Robert W. Cook

Vice President Finance & Chief Financial Officer

Cc: Mr. Dennis Polyn (via facsimile) Ms. Cynthia Webb (via facsimile) Mr. Bruce Zivian (via facsimile)

33 Wood Avenue South, Ste. 466 Iselin, New Jersey 08830 TEL 732-603-3526 FAX 732-603-3532





DSI

April 13, 1998

Box Patent Extension Assistant Commissioner for Patents Washington, D.C. 20231

Re:

Application for Term Extension of

U.S. Patent No. 4,996,335

RECEIVED

JUL - 1 1998

OFFICE OF PETITIONS DEPUTY A/C PATENTS RECEIVED

JUL - 1 1998

PATENT EXTENSION A/C PATENTS

Sir:

- I, Dr. Gad Riesenfeld, as President and Chief Operating Officer of Pharmos Corporation, having general authority from Pharmos Corporation to act on its behalf in patent matters, state as follows:
- 1. Pharmos Corporation, has a place of business 33 Wood Avenue South, Ste. 466, Iselin, New Jersey 08830. Pharmos Corporation was originally incorporated as HGP Inc. in September 1987 and the name changed to Xenon Vision Inc. in September 1989. In October 1992 all of the outstanding stock of Xenon Vision Inc. was obtained b Pharmos Corporation as part of a simultaneous merger of Pharmos Corporation, a New York Corporation, with and into Pharmatec, Inc., a Nevada Corporation. The surviving entity, which is now Pharmos Corporation, was Pharmatec, Inc., which, upon the effectiveness of the October 1992 merger, changed its name to Pharmos Corporation.
- 2. Pharmos Corporation is a licensee of U.S. Patent No. 4,996,335, pursuant to a license agreement with Nicholas S. Bodor, the record owner of U.S. Patent No. 4,996,335. Pharmos Corporation has granted, pursuant to a series of agreements with Bausch & Lomb Pharmaceuticals, Inc., a sub-license under U.S. Patent No. 4,996,335 to Bausch & Lomb Pharmaceuticals, Inc.
- 3. U.S. Patent No. 4,996,335 covers a compound known as loteprednol etabonate, the active ingredient in LOTEMAXTM and ALREXTM.
- 4. Pharmos Corporation participated in the clinical evaluation and registration of LOTEMAXTM and ALREXTM pursuant to NDA 20-583, NDA 20-803 and NDA 20-841 which are owned by Pharmos Corporation.

Box Patent Extension April 13, 1998 Page 2

5. Pharmos Corporation hereby authorizes Nicholas S. Bodor to rely on the activities of Pharmos Corporation pursuant to NDA 20-583, NDA 20-803 and NDA 20-841 to file an application under 35 U.S.C. § 156 for extension of the term of U.S. Patent No. 4,996,335.

Very truly yours,

Dr. Gad Riesenfeld

One Bausch & Lomb Place Rochester NY 14604-2701 716 338 8417 Fax 716 338 6007

Denis A. Polyn Staff Vice President and Assistant General Counsel Patent Law



BAUSCH & LOMB

Healthcare and Optics Worldwide

June 24, 1998

- 1 1998

RECEIVED

PATENT EXTENSION A/C PATENTS



Box Patent Extension Assistant Commissioner for Patents Washington, D.C. 20231 Attention: Ms. Karen Tyson

RE:

Application for Term Extension of

U.S. Patent No. 4,996,335 (the "Patent')

Dear Ms. Tyson:

RECEIVED

JUL - 1 1998

OFFICE OF PETITIONS DEPUTY A/C PATENTS

Reference is made to our letter of April 30, 1998, a copy of which is attached.

As you discussed with Mr. Allan Fanucci, the patent counsel for Pharmos Corporation, and in order to clarify the record, Bausch & Lomb Pharmaceuticals, Inc. ("BLP") is at this time a contingent sublicensee of the Patent. BLP is also a distributor for Pharmos Corporation. That status has been confirmed to you in a letter of June 17, 1998 by Pharmos Corporation. Pharmos Corporation is and remains a licensee of the Patent as stated in our letter of April 13.

We appreciate your willingness to allow us the opportunity to clarify the record. Please do not hesitate to call me at 716-338-8417 should you have any questions.

Sincerely,

DAP:gpm Attachment

CC:

Dr. Gad Riesenfeld (via facsimile)

Ms. Cynthia Webb (via facsimile)

Mr. Bruce Zivian (via facsimile)

Attorney Docket No. PO2019



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Nicholas S. Bodor

U.S. Patent No.: :

4,996,335

Issue Date

February 26, 1991

Application

Serial No.

807,034

Application

Filing Date

December 9, 1985

Inventor

NICHOLAS S. BODOR

For

SOFT STEROIDS HAVING ANTI-INFLAMMATORY ACTIVITY

TRANSMITTAL OF AN APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 USC 156

Box Patent Extension Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

Transmitted herewith is an APPLICATION FOR EXTENSION OF PATENT TERM (including an original and a certified duplicate original and attachments thereto, with a DECLARATION, signed by the Applicant, with a LETTER OF THE SUB-LICENSEE, dated April 23, 1998, signed by Denis A. Polyn, Esq., Assistant General Counsel of the sub-licensee and with a LETTER OF THE LICENSEE, dated April 13, 1998, signed by Dr. Gad Riesenfeld, President and Chief Operating Officer of the licensee) of the above-captioned patent for a product approved on March 9, 1998.



U.S. Patent No. 4,996,335

[X] The APPLICATION FOR EXTENSION OF PATENT TERM is being hand-carried to the U.S. Patent and Trademark Office.

[XI Please charge the prescribed fee in the amount of \$1,120.00 for the application presented to Deposit Account No. 02-1425.

In the event the actual fee differs, it is requested that the overpayment or underpayment be credited or charged to Deposit Account No. 02-1425.

Date April 30, 1998

Denis A. Polyn, Esq.
Bausch & Lomb Inc.
One Bausch & Lomb Place
Rochester, New York 14604-2701
Telephone No. (716) 338-8417
Facsimile No. (716) 338-8706

Respectfully submitted

OFFICE OF PETITIONS

Attachments:

- [X] An original APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 USC 156 and attachments thereto, with a DECLARATION and two LETTERS OF THE LICENSEE and THE SUB-LICENSEE.
- [X] A certified DUPLICATE APPLICATION FOR EXTENSION OF PATENT TERM and attachments thereto, with a DECLARATION and the two LETTERS OF THE LICENSEE and THE SUB-LICENSEE.



U.S. Patent No. 4,996,335

[X] Three (3) working copies of APPLICATION FOR EXTENSION OF PATENT TERM and attachments thereto, with the DECLARATION and two LETTERS OF THE LICENSEE and THE SUB-LICENSEE.

Certified Duplicate

The undersigned hereby certifies that the attached APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 USC 156 for U.S. Patent 4,996,335 and Exhibits are true copies of the original Application for Extension of Patent Term and Exhibits.

RECEIVED

JUL - 1 1993

OFFICE OF PETITIONS DEPUTY A/C PATENTS DENIS A. POLYN REG. NO. 27,152

... UNITED STATES PATENT AND TRADEMARK OFFICE

Page 1 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 1, line 9, "Sept. 18" should read --Sept. 15--.

In Column 2, lines 45-57, delete the structural formula (I), and insert in its stead:

$$\begin{array}{c} X-R_1 \\ C=0 \\ 0 \\ R_3 \\ R_4 \end{array}$$

$$R_3$$

$$(I)$$

In Column 5, line 25, "timethylene" should read --trimethylene--.

UNITED STATES PATENT AND TRADEMARK OFFICE

Page 2 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 5, lines 28 and 29, after "dialkylcarbamoyl", insert --groupings are of the type--.

In Column 10, lines 1-13, delete the structural formula (II) and insert in its stead:

OH
$$C=O$$
 H_3C
 R_3
 R_5
 R_5
 R_5
 R_5
 R_6

UNITED STATES PATENT AND TRADEMARK OFFICE

Page 3 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 10, lines 20-30, delete the structural formula and insert in its stead:

$$CH_2OH$$
 $C=O$
 H_3C
 R_4
 R_5

Page 4 of 59

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 10, lines 50-60, delete the structural formula (III) and insert in its stead:

OH
$$C=O$$
 H_3C
 R_3 "

(III)

UNITED STATES PATENT AND TRADEMARK OFFICE

Page 5 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 11, lines 15-25, delete the structural formula (IV) and insert in its stead:

OM
$$C=0$$
 H_3C
 R_3 "
 R_5
 R_5
 R_5

In Column 12, line 8, "wtih" should read --with--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 6 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 13, lines 1-12, delete structural formula (V) and insert in its stead:

OM
$$C=0$$
 H_3C
 R_4
 R_5
 R_5
 R_5

Page 7 of 59

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 13, lines 18-29, delete the structural formula (VI) and insert in its stead:

OR₁

$$C=O$$
 H_3C
 R_3
 $C=O$
 R_3
 $C=O$
 $C=O$

In Column 13, line 50, after "formula (I) wherein R_1 is", insert --a sulfinyl- or sulfonyl-containing group [e.g., when R_1 is--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 8 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 14, lines 5-17, delete the structural formula (VIII) and insert in its stead:

$$R_{3}$$
C R_{3} " (VIII)

In Column 14, line 42, "phuosgene" should read --phosgene--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 9 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 14, lines 45-57, delete the structural formula (VII) and insert in its stead:

OR₁

$$C=0$$
 H_3C
 R_3 "'

(VII)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 10 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 15, lines 23-34, delete the structural formula (X) and insert in its stead:

HO
$$R_3$$
C R_3 " (X)

In Column 16, line 40, "aceytonitrile" should read --acetonitrile--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 11 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 16, lines 55-68, delete the structural formula (XI) and insert in its stead:

$$\begin{array}{c} O \\ OCOR_2 \\ C=O \\ H_3C \\ R_3 \end{array} (XI)$$

In Column 17, line 25, "suchy" should read --such--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 12 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 17, lines 36-46, delete the structural formula (IX) and insert in its stead:

$$\begin{array}{c|c}
X-R_1 \\
C=0 \\
0 \\
R_3 \\
R_4
\end{array}$$
(IX)

In Column 18, line 20, "and" should read --an--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 13 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 18, line 60, "As" should read --An--.

In Column 20, line 3, "MeKenzie" should read --McKenzie--.

In Column 26, line 63, "asigned" should read --assigned--.

In Column 33, line 24, after "tioned", the period (".") should be a colon

(--:--).

In Column 33, line 32, "propylactic" should read --prophylactic--.

In Column 34, line 39, " $17\alpha/e$ -" should read -- 17α -e- --.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 14 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 35, lines 47-58, delete the structural formula and insert in its stead:

$$HO$$
 H_3C
 H_3C
 H_3C
 H_3C
 H_3C
 H_3C

In Column 35, lines 67-68, "filtration" should read --filtrate--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 15 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 36, lines 12-23, delete the structural formula and insert in its stead:

$$\begin{array}{c} OH \\ C=O \\ H_3C \\ H_3C \\ O \end{array}$$

UNITED STATES PATENT AND TRADEMARK OFFICE Page 16 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 37, lines 15-25, delete the structural formula and insert in its stead:

In Column 37, line 53, after "nmr(CDCl₃)" and before " δ 5.60", insert -- δ 5.80,--. In Column 38, line 24, "mmol6)" should read --mmol)--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 17 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 38, lines 51-61, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 18 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 39, lines 6-16, delete the structural formula and insert in its stead:

$$C=O$$
 $C=O$
 $C=O$

In Column 39, line 22, " 17β -ethoxycarbonyloxy" should read -- 17α -ethoxycarbonyloxy--.

In Column 40, line 18, " 11α , 17β -dihydroxy" should read -- 11β , 17α -dihydroxy--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 19 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 40, lines 35-46, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} OH $C=0$ R_{3} R_{3}

In Column 40, line 48, delete "Compounds".

UNITED STATES PATENT AND TRADEMARK OFFICE Page 20 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

: 4,990,333 February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 40 and 41, in the table in Example 6A, for each of Compound Nos. 6A-1 through 6A-15, under column "Z", at each occurrence,

In Column 41, line 60, at the bottom of the table, before "6a-1 to 6A-15 above", insert --Compounds--.

In Column 41, line 62, " 17α -benzyloxo" should read -- 17α -benzyloxy--.

In Column 43, line 13, "aicd" should read --acid--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 21 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 44, lines 10-21, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} OH $C=0$ R_{3} R_{3}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 22 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 44, 45-46 and 47-48, in the table in Example 6B, for each of Compound Nos. 6B-3, 6B-4, 6B-5, 6B-7, 6B-8, 6B-9, 6B-11, 6B-12, 6B-13, and 6B-15 through 6B-25, under column "Z", at each occurrence,

UNITED STATES PATENT AND TRADEMARK OFFICE Page 23 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 48, lines 15-26, delete the structural formula (VI) and insert in its stead:

OH
$$C=0$$

$$H_3C$$

$$R_3$$

$$R_5$$

UNITED STATES PATENT AND TRADEMARK OFFICE Page 24 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 48 and 49-50, in the table in Example 6C, for each of Compound Nos. 6C-1 through 6C-11, under column "Z", at each occurrence,

UNITED STATES PATENT AND TRADEMARK OFFICE Page 25 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 50, lines 33-45, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} R_{1} $C=0$ R_{2} R_{3}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 26 of 59 CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 50 through 56, in the table in Example 7A, for each of Compound Nos. 7A-1 through 7A-18 and 7A-21 through 7A-30, under column "Z", at each occurrence,

In Column 55, line 20, " 17β -ethoxycarbonyloxy" should read -17α -ethoxycarbonyloxy--.

In Column 56, line 14, "methylandrost" should read --methylandrosta--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 27 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 56, lines 46-56, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} R_{1} $C=0$ R_{2} R_{3}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 28 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 56 through 66, in the table in Example 7B, for each of Compound Nos. 7B-1 through 7B-7, 7B-14 through 7B-18, 7B-22 through 7B-29, 7B-33 through 7B-40, and 7B-44 through 7B-64, under column "Z", at each occurrence,

UNITED STATES PATENT AND TRADEMARK OFFICE Page 29 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 66, lines 40-50, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} R_{5} R_{1} $C=0$ $CCOOR_{2}$ R_{3}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 30 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 66 through 68, in the table in Example 7C, for each of Compound Nos. 7C-1 through 7C-13, under column "Z", at each occurrence,

In Column 69, line 39, " 11α ," should read -11β ,--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 31 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 69, lines 52-62, delete the structural formula and insert in its stead:

$$\begin{array}{c} OR_1 \\ C=O \\ H_3C \\ O \end{array}$$

In Column 70, lines 3-13, delete the structural formula.

In Column 70, line 31, "thylfulfonylmethyl" should read --thylsulfonylmethyl--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 32 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

DATED :

4,996,335

INVENTOR(S):

February 26, 1991 Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 70, lines 37-46, delete the structural formula and insert in its stead:

$$C=0$$
 $C=0$
 $C=0$

UNITED STATES PATENT AND TRADEMARK OFFICE Page 33 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 71, lines 2-11, delete the structural formula and insert in its stead:

$$\begin{array}{c} C1 \\ C=O \\ H_3C \\ H_3C \\ R_4 \end{array}$$

UNITED STATES PATENT AND TRADEMARK OFFICE Page 34 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 71, lines 22-31, delete the structural formula and insert in its stead:

$$C=0$$
 H_3C
 R_4
 R_3
 R_3

UNITED STATES PATENT AND TRADEMARK OFFICE Page 35 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 71, lines 44-54, delete the structural formula and insert in its stead:

$$R_3$$
C R_4 R_5 R_5

UNITED STATES PATENT AND TRADEMARK OFFICE Page 36 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 72, lines 5-13, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 37 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 72, lines 51-60, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 38 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 74, lines 2-14, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 39 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 74, lines 47-55, delete the structural formula and insert in its stead:

In Column 76, line 6, "dikmethylpyrrolidine" should read --dimethylpyrrolidine--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 40 of 59 CERTIFICATE OF CORRECTION

PATENT NO. :

DATED: 4,

4,996,335

INVENTOR(S):

February 26, 1991 Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 76, lines 17-30, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 41 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 76, lines 37-48, delete the structural formula and insert in its stead:

$$\begin{array}{c} OCH_2N \stackrel{+}{\longleftarrow} Cl \stackrel{-}{\longleftarrow} \\ C=O \\ H_3C \\ H_3C \\ O \end{array}$$

UNITED STATES PATENT AND TRADEMARK OFFICE Page 42 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 76, lines 52-55,

In Column 77, lines 3-12, delete the structural formula.

In Column 77, lines 17-20,

In Column 77, lines 57-58, "Benalkonium" should read --Benzalkonium--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 43 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 78, line 38, "Eye Drops" should be underlined.

In Column 79, lines 14-25, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} R_{1} $C=0$ R_{2} R_{3}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 44 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Columns 79-80, lines 24-38, in the table in Example 29, for each of Compound Nos. 29-1 and 29-2, under column "Z", at each occurrence,

UNITED STATES PATENT AND TRADEMARK OFFICE Page 45 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 80, lines 2-12, part (a) of Claim 1, delete the structural formula (I) and insert in its stead:

$$\begin{array}{c}
X - R_1 \\
C = 0 \\
H_3C \\
R_3
\end{array}$$

$$\begin{array}{c}
R_4 \\
R_5
\end{array}$$
(I)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 46 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 81, lines 55-65, part (c) of Claim 1, delete the structural formula and insert in its stead:

$$R_{3}$$
C R_{3} " (III)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 47 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 82, lines 15-24, part (d) of Claim 1, delete the structural formula (IV) and insert in its stead:

$$\begin{array}{c} OM \\ C=O \\ OCOR_2 \\ R_3 \end{array} \qquad (IV)$$

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CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 82, lines 34-44, part (e) of Claim 1, delete the structural formula (VII) and insert in its stead:

$$C=0$$
 H_3C
 R_4
 R_5
 R_5
 R_7
 R_7
 R_7
 R_7
 R_7

UNITED STATES PATENT AND TRADEMARK OFFICE Page 49 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 82, lines 53-64, part (f) of Claim 1, delete the structural formula (VIII) and insert in its stead:

$$R_{3}$$
C R_{3} C R

UNITED STATES PATENT AND TRADEMARK OFFICE Page 50 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 83, lines 2-12, part (g) of Claim 1, delete the structural formula (IX) and insert in its stead:

$$\begin{array}{c|c}
X-R_1 \\
C=0 \\
H_3C \\
R_3
\end{array}$$
(IX)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 51 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 83, lines 20-31, part (a) of Claim 2, delete the structural formula (I) and insert in its stead:

$$\begin{array}{c}
X - R_1 \\
C = 0 \\
H_3C \\
R_3
\end{array}$$

$$\begin{array}{c}
R_4 \\
R_5
\end{array}$$
(I)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 52 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 83, line 49, part (a) of Claim 2, in the definition of R_3 , " β -methyl, β -methyl" should read $-\alpha$ -methyl, β -methyl--.

In Column 84, lines 2-13, part (c) of Claim 2, delete the structural formula (III) and insert in its stead:

$$R_{3}$$
C R_{4} R_{5} R_{5} R_{6} R_{7} R_{7} R_{7} R_{8} R_{7} R_{8} R_{8}

UNITED STATES PATENT AND TRADEMARK OFFICE Page 53 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 84, lines 31-43, part (d) of Claim 2, delete the structural formula (IV) and insert in its stead:

$$\begin{array}{c}
OM \\
C=O \\
OCOR_2 \\
R_3"
\end{array}$$
(IV)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 54 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 84, lines 51-62, part (e) of Claim 2, delete the structural formula (VII) and insert in its stead:

$$R_3$$
C R_4 R_5 R_5 R_6 R_7 R_7

UNITED STATES PATENT AND TRADEMARK OFFICE Page 55 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 85, lines 2-12, part (f) of Claim 2, delete the structural formula (VIII) and insert in its stead:

$$R_{3}$$
C R_{3} " (VIII)

UNITED STATES PATENT AND TRADEMARK OFFICE Page 56 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 85, lines 18-28, part (g) of Claim 2, delete the structural formula (IX) and insert in its stead:

$$X-R_1$$
 $C=0$
 H_3C
 R_3
 R_3
 R_5
 R_5
 R_5

In Column 87, line 16, Claim 50, "sentss" should read --sents--.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 57 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 88, line 42, Claim 73, after "claim 2" and before "is", insert --which--.

In Column 89, line 24, Claim 86, "dien" should read --diene--.

In Column 89, line 53, Claim 95, delete "-I-" and insert -- -O- --.

UNITED STATES PATENT AND TRADEMARK OFFICE Page 58 of 59

CERTIFICATE OF CORRECTION

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 90, lines 33-42, Claim 110, delete the structural formula and insert in its stead:

UNITED STATES PATENT AND TRADEMARK OFFICE Page 59 of 59 **CERTIFICATE OF CORRECTION**

PATENT NO. :

4,996,335

DATED

February 26, 1991

INVENTOR(S):

Nicholas S. BODOR

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 90, lines 52-63, Claim 113, delete the structural formula (I) and insert in its stead:

$$X-R_1$$
 $C=0$
 H_3C
 R_3
 R_4
 R_5
 R_5
 R_5
 (I)

Signed and Sealed this Ninth Day of June, 1998 Attest:

BRUCE LEHMAN

Commissioner of Patents and Trademarks

mey Docket No. PO2019

HE UNITED STATES PATENT AND TRADEMARK OFFICE

cofc

plicant

Nicholas S. Bodor

U.S. Patent No.:

4,996,335

Issue Date

February 26, 1991

Application

Serial No.

807,034

Application

Filing Date

December 9, 1985

Inventor

NICHOLAS S. BODOR

For

SOFT STERIODS HAVING ANTI-INFLAMMATORY ACTIVITY

COMMUNICATION

CERTIFICATE

Box Patent Extension Assistant Commissioner Washington, D.C. 20231 JUN 3 0 1998

OF CORRECTION

SIR:

Transmitted herewith are copies of the following documents:

- (1) Certificate of Correction for U.S. Patent No. 4,996,335;
- (2) Letter from Pharmos Corporation dated June 17, 1998; and,
- (3) Letter from Bausch & Lomb Incorporated dated June 24, 1998.

Respectfully submitted,

Date June 24, 1998

Denis A. Polyn

Reg. No. 27,152

Denis A. Polyn, Esq. Bausch & Lomb, Inc. Rochester, New York 14604-2701

Telephone No. (716) 338-8417 Facsimile No. (716) 338-8706

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited in the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, DC 20231, on June 24, 1998

Grace Mueller